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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,333	08/20/2003	Bernd Disse	01-1196-1-C1	6665

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
09/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/644,333	DISSE, BERND	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11-23 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 11-23 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Remarks filed on 07/08/2010.

- Claims 9 and 32 have been amended.
- Claims 1-8, 10 and 24 have been cancelled.
- Claims 9, 11-23 and 25-32 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 11-15 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerd J Cropp (The American Journal of Medicine, Vol 100, $19-$29, 1996) in view of Peter J. Barnes (Chest, 117(2), 63S-66S, 2000) and Boucher JR (US

2002/0099023) **are maintained** for reasons of record in the previous office action cited on 02/08/2010.

Applicant's arguments filed on 07/08/2010 have been considered but they are not persuasive.

Applicant argues that Gerd ascribes no anti-inflammatory activity to the bronchodilation methods it reviews. This argument is not persuasive since "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The court stated that "just as the discovery of properties of a know material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Id.<See also MPEP s 2112.02 with regard to inherency and rejection under 35 U.S.C. 103. Tiotropium bromide, as well as other salts of tiotropium are known as highly effective anticholinergic bronchodilators and can therefore provide therapeutic benefit in the treatment of COPD. However, tiotropium bromide is also a known anticholinergic bronchodilators for the prevention and treatment of diseases associated with inflammation as evidenced by paragraph 0001 of Disse (US 2002/0193394 A1). See also Hassan et al (US 6,537,524) teaches in illustrative example of a composition claimed in column 6 wherein tiotropium bromide is

used to treat inflammatory or obstructive airways diseases and conditions applicable to acute respiratory distress syndrome, chronic obstructive pulmonary, airways or lung disease (COPD), including chronic bronchitis. Therefore, the examiner reminds applicants that tiotropium bromide salt in the art is known as both anticholinergic bronchodilators as well as anti-inflammatory activity to treat inflammatory component of a disease. Therefore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time the invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Claims 9, 11-14, 21-23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerd J Cropp (The American Journal of Medicine, Vol 100, $19-$29, 1996) in view of Peter J. Barnes (Chest, 117(2), 63S-66S, 2000) and Freund et al (WO 98/27959, for translation an equivalent US 2001/0008632 is used) **are maintained** for reasons of record in the previous office action cited on 02/08/2010.

Claims 9, 11-20 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerd J Cropp (The American Journal of Medicine, Vol 100, S19-S29, 1996) in view of Peter J. Barnes (Chest, 117(2), 63S-66S, 2000), Akehurst et al (US 6,919,069) **are maintained** for reasons of record in the previous office action cited on 02/08/2010.

Applicant argues that none of the cited references provide any suggestion that a tiotropium salt would be useful for "treating an inflammatory component of a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis" or a method where the salt of tiotropium provides an anti-inflammatory activity.

The examiner respectfully points out the following from MPEP 2144.06: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980). As all of the components have been individually shown to be utilized and effective in the treatment of airway obstruction disease, and as all the references demonstrate combinations of the various compounds in a variety of formulations, the combination of all/or any of the claimed compounds is rendered obvious by the prior art. One would have been motivated to perform such combinations in expectation of achieving better treatments for airway obstruction associated with cystic fibrosis. Gerd teaches bronchodilators such as adrenergics and parasymptholytic agents that have been used for years in the treatment of airway obstruction associated with cystic fibrosis. In general, most patients with cystic fibrosis are likely to benefit from bronchodilator therapy when given in adequate doses, appropriate combinations, and by the appropriate route (abstract). Peter reference is relied upon tiotropium is approximately 10-fold more potent than ipratropium as muscarinic receptors, Freund reference is relied upon for the pharmaceutical

preparations in the form of aqueous solutions of the production of propellant-free aerosols for inhalation for the therapy of obstructive lung diseases and, Akehurst relied upon a pharmaceutical aerosol formulation comprising particulate medicament (anticholinergics e.g. ipratropium, atropine or oxitropium), 1,1,1,2-tetrafl uoroethane (TG 134a), 1,1,1,2,3,3,3-heptafluoro-n-propane (TG227) and polar co-solvents such as aliphatic alcohols and polyols.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618